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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/719,211 | 11/21/2003 | Daniel Joseph Burch | P50383D2 | 2764 |

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| EXAMINER | |
|---|---|
| JAGOE, DONNA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/719,211 | BURCH ET AL. | |
| | Examiner | Art Unit | |
| | Donna Jagoe | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



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## DETAILED ACTION

***Claims 16-43 are presented for examination.***

### *Specification*

The spacing of the lines of the specification is such as to make reading difficult. New application papers with lines 1½ or double spaced on good quality paper are required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39 40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites the limitation "the container as claimed in claim 301" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim because there is not a claim 301 in the case.

The remaining claims (40 and 42) are indefinite to the extent that they read on the rejected base claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of any one of Lawrence et al. (1985) Genitourin. Med. 61: 168-71 or

Osoba et al. (*1985) Afr. J. Med. Med. Sci. 14: 169-173 taken with Vartan U.S. Patent No. 5,114,929

The instantly claimed invention is drawn to a container comprising a powder or granular product for reconstitution into a suspension or solution comprising amoxycillin 600mg and clavulanate having a ratio of 14:1 +/- 5% (amoxycillin to clavulanate). Lawrence et al (1985) teach a powder formulation (sachet) of amoxycillin clavulanate (3g amoxycillin to 125 mg and 250 mg of clavulanate) for suspension in liquid for oral administration (see abstract and introduction to patients and methods of pages 168-169). Both regimens are taught to provide similar efficacy in treating patients suffering from Neisseria gonorrhea infection. However, the reference notes that more patients in the regimen using 250 mg of clavulanate had adverse side effects as compared to those on 125 mg regimen and no obvious advantage to the use of higher concentration of clavulanate (last paragraph of abstract and page 168 and page 171, first column).

Similarly, Osoba et al. (1985) teach the two amoxycillin clavulanate regimens to treat Neisseria gonorrhea infection. Osoba et al. found better efficacy with the 250 mg clavulanate in the formulation as compared to 125 mg. See Tables 1 and 2 on page 171. Since increasing the clavulanic acid above to 250 mg in the augmentin formulation may lead to gastrointestinal symptoms, Osoba et al. suggest increasing amoxycillin to 3.5 or 4.0 g in order to improve the efficacy of the formulation (last paragraph, page 173).

As such, it would have been obvious to one or ordinary skill in the art at the time of the Applicant's invention to use an Augmentin formulation having a ratio of 14:1 +/-

5% amoxycillin to clavulanate given the teachings of Lawrence et al. or Osoba et al. since the references teach that the rations of 12:1 and 24:1 were effective or similarly effective against the treatment of N. gonorrhea infection with the reasonable expectation of decreasing any possible adverse side effects as compared to 12:1 as suggested by Lawrence et al. or to improve the efficacy of the formulation as suggested by Osoba et al. Note that Osoba et al. explicitly suggest a ratio of 14:1 amoxycillin/clavulanate. See the last paragraph on page 173 or Osoba et al. While the references do not particularly recite the concentrations of the amoxycillin in the suspended formulations of from about 500 mg to about 700 mg/5 ml, the dry powder formulations taught by the prior art have the capability of providing this concentration depending on the volume of liquid added by the administrator based upon solubility and the rate of administration, well known to those skilled in the art. Regarding claims to a container, it is a standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use in a package. Further, since the composition is intended for reconstitution with a liquid diluent, such as water, it would have been obvious to enclose the powder or granular product in a moisture proof container motivated by the well-known fact that non-moisture proof containers get soggy and leak when a liquid diluent is added. Regarding claims drawn to an edible desiccant, Vartan teaches silicon dioxide as an edible desiccant, added to, for example, amoxicillin trihydrate and potassium clavulanate (see column 2, line 62 to column 3, line 23).

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-43 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,814,337. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 16-43, drawn to a container comprising a powder or granular product for reconstitution into a suspension or solution comprising amoxycillin 600mg and clavulanate having a ratio of 14:1 +/- 5% (amoxycillin to clavulanate). Claims to Merrifield are drawn to a pharmaceutical formulation having a composition within (12:1) +/- 10% consisting of 25% w/w amoxycillin trihydrate and 2.08% potassium clavulanate among other additives. See the patent claim 3, for instance. Since the ratio of amoxycillin to clavulanate of the patented claim is 12:1 +/- 10%, the patented claims encompassed a range of 22.5 to 27.5% of amoxycillin to 1.8 to 2.2% potassium clavulanate, with a range of (9.8-14.7) amoxycillin to 1 clavulanate which overlaps with the instantly claimed range of 14:1 +/- 5% and constitute an obvious variation of the

earlier patented invention. The patent claim does not specify the intended route of administration nor the intended concentration. Nevertheless, it is apparent from the claimed language that the patented formulation is adapted for oral administration (note the flavoring agents present in the composition of claim 3, for instance, of '337). Further, the formulation is capable of being constituted in any concentration including 500 to about 700 mg amoxycillin/5ml as the concentration is based upon the amount of water/liquid added prior to suspension. As such, it would have been obvious to one or ordinary skill in the art to optimize the concentrations of amoxycillin/clavulanate ratios to 14:1 +/- 5% given the patented claim to treat susceptible microbes as it is routine in the antibiotic art to optimize efficacy for the organisms to be treated wit respect to dosage and the frequency, as well as other pertinent parameters, with the reasonable expectation of killing or treating the susceptible microbes. It is noted that the absolute amounts for the antibiotic amoxycillin appear to be different in the comparative vs. test. Note on page 5, lines 6-8 of the instant specification describing the Figures wherein the 14:1 ratio had 45:3.2 mg/kg and the comparative had 22.5:3.2 mg/kg. Since the antibiotic amoxycillin provides antibiosis, it would appear to be an expected result to obtain higher antibiosis with higher doses. Regarding the container, it is a standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use in a package.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-

0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
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10/02/2005

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